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Montreal, August 17, 2005

Commissioner of Patents
CANADIAN RECEIVING OFFICE
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Re : International Application No. PCT/CA2004/001851
Filed on October 21, 2004
Title : COMBINED POSITIVE AND NEGATIVE
PRESSURE ASSIST VENTILATION
Applicant : MAQUET CRITICAL CARE AB et al.
Our file : 08831-007

Dear Sir:

This is in response to the International Search Report mailed on March 2nd, 2005, and to the Written Opinion accompanying this International Search Report.

BOX No. V

In this Written Opinion, the following references were cited:

D1 = US 4 481 938
D2 = WO 99/43374
D3 = WO 01/08735
D4 = US 5 871 008

I. Novelty:

In the written opinion, the combination of features disclosed in claims 1 to 50 is considered to be novel as no reference discloses all the elements and limitations of the claimed device and method. The subject matter of claims 1-50 is accordingly considered as complying with PCT Article 33(2).

II. Inventive Step:

In the written opinion:

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 **MERITAS**
LAW FIRMS WORLDWIDE

- the subject matter of claims 1 to 3, 12, 23, 24, 30 to 32 and 40 is not deemed to fulfil the requirements of PCT Article 33(3), in view of document D1;
- the subject matter of claims 4, 5, 25, 28, 33 and 34 is not deemed to fulfil the requirements of PCT Article 33(3), in view of documents D1 and D2;
- the subject matter of claims 6 to 10, 26 and 35 to 38 is not deemed to fulfil the requirements of PCT Article 33(3), in view of documents D1 and D3;
- the subject matter of claims 14 to 16, 18, 19, 29, 42 to 44, 46 and 47 is not deemed to fulfil the requirements of PCT Article 33(3), in view of documents D1 and D4; and
- the combination of features disclosed in dependent claims 11, 13, 17, 20 to 22, 27, 39, 41, 45 and 48 to 50 is not disclosed in the available prior art and involves an inventive step over the available prior art.

To overcome the above rejections, enclosed herewith is a newly submitted set of claims in which:

- independent claims 1, 23 (newly renumbered as claim 22) and 30 (newly renumbered as claim 29) have been amended;
- new independent claims 10 and 37 have been added to better define the invention; and
- the numbering, dependency and wording of the other claims have been modified to take into consideration the above indicated amendments to the independent claims.

The following table establishes the correspondence between the original claims and the newly submitted claims:

NEWLY SUBMITTED CLAIMS	ORIGINAL CLAIMS	NEWLY SUBMITTED CLAIMS	ORIGINAL CLAIMS
1	1 +12	26	27
2	3	27	28
3	4	28	29
4	5	29	30
5	6	30	32
6	7	31	33
7	8	32	34
8	9	33	35
9	10	34	36

10	1 + 11	35	37
11	11	36	38
12	13	37	30 + 39
13	14	38	39
14	15	39	40
15	16	40	41
16	17	41	42
17	18	42	43
18	19	43	44
19	20	44	45
20	21	45	46
21	22	46	47
22	23	47	48
23	24	48	49
24	25	49	50
25	25		

In the newly submitted set of claims, independent claim 1 has been amended to introduce the subject matter of former claim 11 and therefore recite an operation of synchronizing triggering and termination of the application of negative pressure around the patient's ribcage and/or abdomen with triggering and termination of the application of positive pressure to the patient's airways. The corresponding independent system claim 29 has been amended accordingly.

Document D1 describes a resuscitator designed to apply both positive and negative pressure ventilatory support to a patient. The resuscitator of document D1 is designed as a single unit whereby, in operation, both positive and negative pressures are applied according to a predetermined scheme related to the design of the unit. There is no teaching in document D1 that the triggering and termination of the application of negative pressure around the patient's ribcage and/or abdomen can eventually be synchronized with triggering and termination of the application of positive pressure to the patient's airways.

Newly submitted claim 22 (former claim 23) has been amended to recite at least one sensor for detecting at least one patient's respiratory related feature, and a controller supplied with said at least one patient's respiratory related feature and connected to the positive and negative pressure ventilators for controlling operation of said positive and negative ventilators in relation to said patient's at least one respiratory related feature.

For the following reasons, Documents D1-D4, taken separately or in combination, fail to describe such a controller responsive to a patient's respiratory related feature to control both the positive and negative pressure ventilators. More specifically, document D1 discloses a resuscitator designed as a single unit whereby, in operation, both positive and negative pressures are applied according to a predetermined scheme related to the

design of the unit; the application of positive and negative pressures is not related to a patient's respiratory related feature. Document D2 describes a method and device for triggering positive pressure ventilatory support in response to a patient's respiratory related feature. Document D3 describes a ventilation controller responsive to both a patient's respiratory related feature and a target value of this feature to control the positive pressure produced by a ventilator. Finally, document D4 describes a miniature high frequency ventilator to apply negative pressure ventilatory support to a patient. In document D4, a required pressure swing was determined from the volume range specification to determine a predicted tidal volume and, from this tidal volume, to find required pressure range needed to design the respirator. Therefore, contrary to the examiner's comments, it is respectfully submitted that the pressure swing is not measured to adjust the level of negative pressure applied to the patient; the pressure swing was determined to design the respirator.

An independent claim 10 has been added to recite a method of delivering combined positive and negative pressure assist ventilation to a patient, comprising: applying a positive pressure to the patient's airways to inflate the patient's lungs; applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs, wherein applying the negative pressure comprises adjusting the negative pressure to a value selected from the group consisting of a constant value and a value related to a patient's respiratory related feature; and synchronizing application of the positive and negative pressures.

A system claim 37 corresponding to method claim 10 has also been introduced in the set of claims.

It is respectfully submitted that there is no teaching in documents D1-D4, taken separately or in combination, that in a method and device for delivering combined positive and negative pressure assist ventilation to a patient, the negative pressure can be adjusted to a value selected from the group consisting of a constant value and a value related to a patient's respiratory related feature (see the above arguments regarding documents D1-D4).

BOX No. VIII

Since incorporations by reference of documents is accepted in many countries, the objection raised by the examiner under PCT Article 5 will be dealt with during the national and regional phases of the present international patent application.

The term "patient's ribcage and/or abdomen" is believed to be the only term suitable to described application of a negative pressure around the patient's ribcage, around the patient's abdomen or around both the ribcage and abdomen. Since the negative pressure can be applied either around the patient's ribcage, around the patient's abdomen or around both the ribcage and abdomen, the term "patient's ribcage and/or abdomen" is

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required to allow the applicant to obtain the scope of protection to which they are entitled for their invention.

The claims have been amended to overcome the examiners objection to claims 4, 6, 11 to 14, 21, 22 and 49 as being indefinite and failing to comply with PCT Article 6.

It is respectfully requested that the above amendments be made of record in the international patent application.

In view of the above amendments and remarks, reconsideration of the present patent application is respectfully requested.

Yours very truly,

BKP GP (formerly BROUILLETTE KOSIE PRINCE)



Gaétan Prince

GP/Ir
Encls.

WHAT IS CLAIMED IS:

1. A method of delivering combined positive and negative pressure assist ventilation to a patient, comprising:
 - 5 applying a positive pressure to the patient's airways to inflate the patient's lungs;
 - applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs; and
 - 10 synchronizing triggering and termination of the application of negative pressure around the patient's ribcage and/or abdomen with triggering and termination of the application of positive pressure to the patient's airways.
2. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 1, comprising:
 - 15 adjusting levels of the positive and negative pressures to avoid application of excessive positive pressure to the patient's airways and thereby minimize hemodynamic adverse effects.
- 20 3. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 1, wherein applying the positive pressure to the patient's airways comprises:
 - detecting neural inspiratory activation of the patient; and
 - applying positive pressure to the patient's airways as a function of the
 - 25 detected neural inspiratory activation.
4. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 3, comprising:
 - 30 synchronizing triggering and termination of the application of the positive pressure to the patient's airways as a function of the detected neural inspiratory activation.

5. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 1, wherein applying the positive pressure to the patient's airways comprises:

- 5 determining a target level of neural inspiratory activation of the patient;
- detecting a level of neural inspiratory activation of the patient;
- comparing the detected level of neural inspiratory activation with the determined target level; and
- controlling a level of positive pressure applied to the patient's airways as a function of the comparison.

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6. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 5, comprising:

- 15 synchronizing triggering and termination of the application of the positive pressure to the patient's airways in relation to the detected level of neural inspiratory activation.

7. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 5, wherein controlling the level of positive pressure applied to the patient's airways comprises:

- 20 increasing the level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is higher than the determined target level.

- 25 8. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 5, wherein controlling the level of positive pressure applied to the patient's airways comprises:

 decreasing the level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is lower than the determined target level.

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9. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 5, wherein controlling the level of positive pressure applied to the patient's airways comprises:

5 maintaining a present level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is equal to the determined target level.

10. A method of delivering combined positive and negative pressure assist ventilation to a patient, comprising:

10 applying a positive pressure to the patient's airways to inflate the patient's lungs;

15 applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs, wherein applying a negative pressure comprises adjusting the negative pressure to a value selected from a group consisting of a constant value and a value related to a patient's respiratory related feature; and

synchroizing application of the positive and negative pressures.

20 11. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 10, wherein applying the negative pressure around the patient's ribcage and/or abdomen comprises:

applying a constant negative pressure around the patient's ribcage and/or abdomen during patient's inspiration.

25

12. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 10, wherein applying the negative pressure around the patient's ribcage and/or abdomen comprises:

detecting neural inspiratory activation of the patient; and

30 applying the negative pressure around the patient's ribcage and/or abdomen as a function of the detected neural inspiratory activation.

13. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 10, wherein applying the negative pressure around the patient's ribcage and/or abdomen comprises:

5 determining a target level of an abdominal pressure swing of the patient;

detecting a level of abdominal pressure swing of the patient;

comparing the detected level of abdominal pressure swing with the determined target level; and

10 controlling a level of negative pressure applied around the patient's ribcage and/or abdomen as a function of the comparison.

14. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 13, wherein controlling the level of negative pressure applied around the patient's ribcage and/or abdomen

15 comprises:

increasing the level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates that the detected level of abdominal pressure swing of the patient is higher than the determined target level.

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15. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 13, wherein controlling the level of negative pressure applied around the patient's ribcage and/or abdomen comprises:

25 decreasing the level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates that the detected level of abdominal pressure swing of the patient is lower than the determined target level.

30 16. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 13, wherein controlling the level of

negative pressure applied around the patient's ribcage and/or abdomen comprises:

5 maintaining a present level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates that the detected level of abdominal pressure swing of the patient is equal to the determined target level.

10 17. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 10, further comprising applying a constant Negative End-Expiratory Pressure over the abdomen to adjust an end-expiratory lung-volume.

15 18. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 17, comprising applying the constant Negative End-Expiratory Pressure over the abdomen in combination with inspiratory negative pressure assist ventilation.

20 19. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 17, comprising applying the constant Negative End-Expiratory Pressure over the abdomen in proportional response to tonic inspiratory muscle activation occurring during expiration.

25 20. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 10, wherein applying the negative pressure comprises obtaining an intrathoracic pressure estimate by measuring an airway pressure deflection during a patient's airway occlusion.

30 21. A method of delivering combined positive and negative pressure assist ventilation as defined in claim 20, wherein, in case of intrinsic PEEP, obtaining the intrathoracic pressure estimate includes an extrapolation for the period between an onset of electrical activity of the patient's diaphragm activity and an onset of the patient's airway pressure deflection.

22. A system for delivering combined positive and negative pressure assist ventilation to a patient, comprising:

- at least one sensor for detecting at least one patient's respiratory related feature;
- 5 a positive pressure ventilator connected to the patient's airways for applying a positive pressure to the patient's airways to inflate the patient's lungs;
- 10 a negative pressure ventilator installed on the patient's ribcage and/or abdomen for applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs; and
- 15 a controller supplied with said at least one respiratory related feature, and connected to the positive and negative pressure ventilators for controlling operation of said positive and negative pressure ventilators in relation to said at least one patient's respiratory related feature.

23. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, wherein the controller operates the positive and negative pressure ventilators to synchronize triggering and

- 20 termination of the application of negative pressure around the patient's ribcage and/or abdomen with triggering and termination of the application of positive pressure to the patient's airways.

24. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, comprising a sensor of neural inspiratory activation of the patient, the controller being responsive to the neural inspiratory activation detected by the sensor to control the positive pressure ventilator.

30 25. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, comprising:

means for supplying a target level of neural inspiratory activation of the patient; and

a sensor of neural inspiratory activation of the patient;

wherein the controller comprises a comparator of the detected level of
5 neural inspiratory activation with the determined target level to control the positive pressure ventilator in relation to this comparison.

26. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, wherein the controller controls the
10 negative pressure ventilator to apply a constant negative pressure around the patient's ribcage and/or abdomen during patient's inspiration.

27. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, comprising:

15 a sensor of neural inspiratory activation of the patient;
wherein the controller is responsive to the neural inspiratory activation
to control the negative pressure ventilator.

28. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 22, comprising:

means for supplying a target level of an abdominal pressure swing of
the patient; and
a sensor of a level of abdominal pressure swing of the patient;
the controller comprising a comparator of the detected level of
25 abdominal pressure swing with the determined target level to control the negative pressure ventilator as a function of the comparison.

29. A system for delivering combined positive and negative pressure assist ventilation to a patient, comprising:

30 first means for applying a positive pressure to the patient's airways to inflate the patient's lungs;

second means for applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs; and

means connected to the first and second pressure applying means for

5 synchronizing triggering and termination of the application of negative pressure around the patient's ribcage and/or abdomen with triggering and termination of the application of positive pressure to the patient's airways.

30. A system for delivering combined positive and negative pressure

10 assist ventilation as defined in claim 29, comprising:

means for adjusting levels of the positive and negative pressures to avoid application of excessive positive pressure to the patient's airways and thereby minimize hemodynamic adverse effects.

15 31. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 29, wherein the first means comprises:

means for detecting neural inspiratory activation of the patient; and

means for applying positive pressure to the patient's airways as a function of the detected neural inspiratory activation.

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32. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 31, wherein the synchronizing means comprises:

means for synchronizing triggering and termination of the application of

25 the positive pressure to the patient's airways as a function of the detected neural inspiratory activation.

33. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 29, wherein the first means comprises:

30 means for determining a target level of neural inspiratory activation of the patient;

means for detecting a level of neural inspiratory activation of the patient;

means for comparing the detected level of neural inspiratory activation with the determined target level; and

5 means for controlling a level of positive pressure applied to the patient's airways as a function of the comparison.

34. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 33, wherein the controlling means
10 comprises:

means for increasing the level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is higher than the determined target level.

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35. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 33, wherein the controlling means comprises:

means for decreasing the level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is lower than the determined target level.

36. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 33, wherein the controlling means
25 comprises:

means for maintaining a present level of positive pressure applied to the patient's airways when the comparison indicates that the detected level of neural inspiratory activation of the patient is equal to the determined target
30 level.

37. A system for delivering combined positive and negative pressure assist ventilation to a patient, comprising:

first means for applying a positive pressure to the patient's airways to inflate the patient's lungs;

5 second means for applying a negative pressure around the patient's ribcage and/or abdomen in order to reduce a load imposed by the ribcage and/or abdomen on the patient's lungs, comprising means for adjusting the negative pressure to a value selected from a group consisting of a constant value and a value related to a patient's respiratory related feature; and

10 means for synchronizing the operation of the first and second pressure-applying means.

38. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, wherein the second means 15 comprises:

means for applying a constant negative pressure around the patient's ribcage and/or abdomen during patient's inspiration.

39. A system for delivering combined positive and negative pressure 20 assist ventilation as defined in claim 37, wherein the synchronizing means comprises:

means for synchronizing triggering and termination of the application of negative pressure with triggering and termination of the application of positive pressure.

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40. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, wherein the second means 30 comprises:

means for detecting neural inspiratory activation of the patient; and

means for applying the negative pressure around the patient's ribcage and/or abdomen as a function of the detected neural inspiratory activation.

41. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, wherein the second means comprises:

- means for determining a target level of an abdominal pressure swing of the patient;
- 5 means for detecting a level of abdominal pressure swing of the patient;
- means for comparing the detected level of abdominal pressure swing with the determined target level; and
- means for controlling a level of negative pressure applied around the patient's ribcage and/or abdomen as a function of the comparison.
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42. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 41, wherein the controlling means comprises:

- 15 means for increasing the level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates that the detected level of abdominal pressure swing of the patient is higher than the determined target level.

20 43. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 41, wherein the controlling means comprises:

- means for decreasing the level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates that the 25 detected level of abdominal pressure swing of the patient is lower than the determined target level.

30 44. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 41, wherein the controlling means comprises:

- means for maintaining a present level of negative pressure applied around the patient's ribcage and/or abdomen when the comparison indicates

that the detected level of abdominal pressure swing of the patient is equal to the determined target level.

45. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, further comprising means for applying a constant Negative End-Expiratory Pressure over the abdomen to adjust an end-expiratory lung-volume.

46. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 45, wherein the constant Negative End-Expiratory Pressure applying means comprises means for applying the constant Negative End-Expiratory Pressure over the abdomen in combination with inspiratory negative pressure assist ventilation.

47. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 45, wherein the constant Negative End-Expiratory Pressure applying means comprises means for applying the constant Negative End-Expiratory Pressure over the abdomen in proportional response to tonic inspiratory muscle activation occurring during expiration.

48. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 37, wherein the means for applying a negative pressure comprises means for obtaining an intrathoracic pressure estimate by measuring an airway pressure deflection during an occlusion of the patient's airway.

49. A system for delivering combined positive and negative pressure assist ventilation as defined in claim 48, wherein, in case of intrinsic PEEP, the intrathoracic pressure estimate obtaining means comprises means for conducting an extrapolation of the intrathoracic pressure estimate for the period between an onset of electrical activity of the patient's diaphragm activity and an onset of the patient's airway pressure deflection.